

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

705

Refer to: 1122388

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

December 5, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James McClaughry, President
Lee's Gas Supplies, Incorporated
9113 Industry Drive
Manassas Park, Virginia 22111

Dear Mr. McClaughry:

During an inspection of your facility conducted by the Food and Drug Administration (FDA) November 18 to 20, 1997, deviations from current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations(CFR), Part 211) were observed in your firm's Oxygen U.S.P. operation. The deviations observed render your firm's Oxygen U.S.P. products adulterated within the meaning of Section 501(a)(2)(B) of the Federal, Food, Drug and Cosmetic Act. The deviations include the following:

1. Failure to perform adequate prefill operations on each high-pressure cylinder prior to filling.
2. Failure to maintain adequate batch production records for each batch of Oxygen U.S.P. produced.
3. Failure to calibrate gauges and thermometers used in filling oxygen.
4. Failure to document that employees involved in filling oxygen have been adequately trained.
5. Failure to establish written procedures designed to assure that your Oxygen U.S.P. has the identity and purity that it is represented to possess.

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6. Failure to establish adequate Standard Operating Procedures (SOPs) for filling compressed oxygen.
7. Failure to follow written procedures for production and process controls regarding lot numbers and supervisory record review.
8. Failure to assure that a qualified individual is responsible for your quality control unit.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

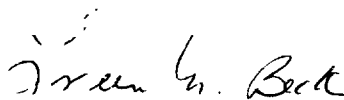
By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, attention: Wiley T. Williamson III, Compliance Officer. Mr. Williamson can be reached at 410-962-4366, Extension 136.

Sincerely,



Loveen M. Beck

Acting Director, Baltimore District